NewMexico

OCT 15 2008

510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number K 082336

I. Applicant Information

Applicant:

NEW MEXICO SOFTWARE INC.
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U.S.A.

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Technology & Development Vice President
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Application Correspondent:

EMERGO GROUP INC.
1705 S. Capital of Texas Hwy., Suite 500
Austin, TX 78746
U.S.A.

Contact Person: Neal Kolber
Project Manager
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Date Prepared: August 5, 2008

II. Device Name and Classification

Proprietary Name:	XR-EXpress
Common/Usual Name:	Soft-copy reading and acquisition system
Classification Name:	Picture Archiving Communications System (PACS)
Regulation Number:	892.2050
Product Codes:	LLZ
Classification:	Class II
Classification Panel:	Radiology Devices

III. Predicate Device

The XR-EXpress device is substantially equivalent to the following FDA cleared predicate device with regard to indications for use, performance and technological characteristics:

510(k) Number:	K063221
Trade Name:	Advanced 3D Web PACS™
Manufacturer:	Nexsys Electronics, Inc. DBA Medweb LLC
Common/Usual Name:	Soft-copy reading and acquisition system
Classification Name:	Picture Archiving Communications System (PACS)
Regulation Number:	892.2050
Product Codes:	LLZ
Classification:	Class II

IV. Description and Intended Use of the Device

XR-EXpress is a PACS and teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. XR-EXpress is for hospitals, imaging centers, nursing homes, radiologist reading practices, and any user who requires and is granted access to patient image, demographic, and report information.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Moreover, it is the user's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with the clinical application.

The software does not contact the patient, nor does it control any life-sustaining devices. A physician has ample opportunity for competent human intervention while interpreting images and clinical information.

V. Summary of the Technical Characteristics

The XR-EXpress system is comprised of a capture component (XR-EXpress Capture), a central server component (XR-EXpress Server), and a viewer component (XR-EXpress Viewer) that is used on general purpose computing hardware. Patient information, procedure information, and image acquisition data is captured by XR-EXpress Capture and sent to the XR-EXpress server or

alternatively, it is accepted directly from a DICOM compliant device. After receiving image objects and associated data, the XR-EXpress server registers the incoming data and images with the archive including any associations with prior cases. The cases are presented to users with the correct permissions from a work list as controlled by a managing user. The image data is transmitted and rendered on the users workstation using a standard web browser for management views or the XR-EXpress Viewer for diagnosis. After using the workstation to view the images, the user optionally dictates a report into the system, after which, a user can play back the dictation and transcribe it to text. Once the XR-EXpress Server registers a report, the report is available to the referring physician or client service where it available electronically or via fax.

VI. Testing

New Mexico Software has conducted extensive validation testing of the XR-EX System, as a PACS system that is capable of providing reliable tele-radiology services over the Internet. All of the different components of the XR-EX system have been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate safely and effectively.

VII. Safety & Effectiveness Conclusions

Based on the intended use and technological characteristics, the XR-EXpress system is substantially equivalent to the Advanced 3D Web PACS™ device manufactured by Nexsys Electronics, Inc. DBA Medweb LLC (K063221). The XR-EXpress raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

New Mexico Software, Inc.
% Mr. Neal Kolber
Project Manager
Emergo Group, Inc.
1705 S. Capital of Texas Hwy., Suite 500
AUSTIN TX 78746

Re: K082336
Trade/Device Name: XR-EXpress
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 5, 2008
Received: August 15, 2008

Dear Mr. Kolber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indication for Use Statement

510(k) Number (if known): K082336

Device Name: **XR-EXpress**

Indications for Use:

XR-EXpress is a PACS and teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. XR-EXpress is for hospitals, imaging centers, nursing homes, radiologist reading practices, and any user who requires and is granted access to patient image, demographic, and report information.

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Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082336